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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,196	10/09/2002	Uwe Ries	5/1266	8098

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EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/19/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,196

Applicant(s)

RIES ET AL.

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,11 and 12 is/are rejected.
- 7) ☒ Claim(s) 2,3,6-8,13 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 5, 1-4, 6-8, 11-14 in part, drawn to compounds and pharmaceutical compositions and method of treating, wherein Ar is a phenylene or a naphthylene and R1 is 5 or 6 membered hetero ring (pyrrolidine or piperidine) linked to the phenyl ring via a carbonyl and m is 0.

Group II, claim(s) 1-4, 6-8, 11-14 in part drawn to compounds and pharmaceutical compositions and method of treating, wherein Ar is a phenylene or a naphthylene and R1 is an amino sulphonyl phenyl, m is 0.

Group III, claim(s) 1-3, 6-8, 11-14 in part, drawn to compounds, pharmaceutical composition and method of treating where in Ar is a thienylene, thiozolyene and R1 is a non-hetero ring containing group, m is 0.

Group IV, claim(s) 1-3, 6-8, 11-14, all in part drawn to compounds, pharmaceutical compositions and method of treating wherein Ar is a pyridinyl, pyrimidinylene, pyrazinylene or pyridazinylene and R1 is a non-hetero ring containing group m is 0.

Group V, claim(s) 1-3, 6-8, 11-14, all in part drawn to compounds, pharmaceutical compositions and method of treating drawn to R1 and Ar variables different than in groups I-IV. A further election of a single disclosed species is required. This group may be further subject to restriction.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) "Markush Practice." The situation involving the so-called "Markush practice" wherein a single claim defines alternatives (chemical or non-chemical) is also governed by Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or

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corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) all alternatives have a common property or activity, **and**

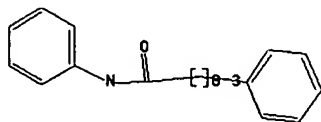
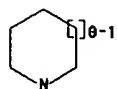
(B)(1) a common structure is present, i.e., a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

(ii) In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of the existing prior art. The structural element may be a single component or a combination of individual components linked to-gether.

The different Ar, R1-R5 substituents have so many variables with the heterocyclic and non-hetero groupings, they have different bonding and properties, and have achieved a different status in the art, and is burdensome to search and hence are objected to as being drawn to an improper Markush group on the grounds of lack of a common nucleus. The terms Ar and R1-R5 are so broad in scope that a prior art reference anticipating the claims with respect to one member under 35 USC 102(b) would not render obvious the same claims under 35 USC 103a with respect to another member.

A preliminary search on the core gave numerous iterations indicating that the core is not the applicants contribution over the prior art.!



=> s 11 ful

FULL SEARCH INITIATED 18:09:53 FILE 'REGISTRY'

FULL SCREEN SEARCH COMPLETED - 198898 TO ITERATE

During a telephone conversation with Mr. David Dow on 8/14/2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 5, 1-4, 6-8, 11-14 in part. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims drawn to groups II-V are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art , the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are required to amend the claims to the elected group.
Applicants preserve their right to file a divisional on the canceled non-elected claims , without prejudice in due course.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for carboxy and amino and imino , does not reasonably provide enablement for any group converted to a carboxy and any group replacing the amino

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and the imino group!! The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without any undue experimentation.

In re Wands , 858 F. 2d 731,737,8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Ex Parte Forman, 230 USPQ 546 (Bd of App. 1986).

The breadth of the claim is so large with any group and there is very little predictability in the art which groups would cleave or which could replace the amino and the imino group, that without guidance one would require an undue amount of experimentation to replace the carboxy and amino and imino groups!!!

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 , 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 and 5 recites the limitation "of the pyrrolidinyl carbonyl, and piperidinyl carbonyl" . There is insufficient antecedent basis for this limitation in the claim. There is no indication in claims that R1 is a hetero ring linked via a carbonyl to the phenyl ring!

Also claim 1 recites for the definition of R5, "R5 denotes a cyano group or an amidino group... , said heteroaryl groups...."

It is unclear what applicants mean by the heteroaryl group in R5!

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Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "said amidino group"

Applicants can overcome this by inserting R5 is an amidino group.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites by a group which is negatively charged under physiology conditions does not clearly indicate which groups the applicants mean.

Also claim 12 recites "the amino and imino groups are replace by a group that may be cleaved" does not clearly define which groups the applicants mean. The meets and bounds of the group are not clearly defined.

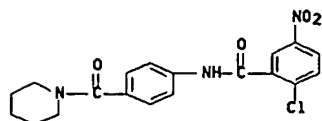
Conclusion

The compounds are allowable over the prior art.

Closest prior art :-

WO 2003035602 ,5/01/2003, Amemiya, Yoshiya et al.

which discloses compounds of the formula



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these do not have a cyano group , nor the amidino group on the phenyl ring . Also the carbonyl is directly linked to the Ar group, in other words m and n both are zero. This is after the applicants priority date.

WO 2002062748 even though filed after Nov 2000 is not published in English.

but on page 2 does disclose similar compounds

~~2-(5-Carbamimidoyl-2-hydroxy-phenyl)-N-(3-chloro-4-(pyrrolidin-1-yl-carbonyl)-phenyl)-acetamid.~~

Thus the claims are allowable over the prior art.

If applicants overcome the 112 issues and amend the claim to the elected group the claims may be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 703-305-1868. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Rita J. Desai
Primary Examiner
Art Unit 1625

R.D.
8/15/2003.